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ABSTRACT

The Health Level 7 Reference Information Model 3.0 (HL7 RIM) has been developed to describe all of the data for health care systems. We describe a process followed to integrate the HL7 RIM into a clinical Laboratory Information Management System (LIMS). The methodology included interviewing users, reviewing data from clinical studies, developing a look-and-feel prototype of user-interfaces, development of an entity-relationship (ER) diagram based solely on clinical system requirements, evaluation of the HL7 RIM, integration of HL7 RIM into a revised ER diagram, and implementation of a database and web-based LIMS prototype. Substantial difficulty was encountered due to the abstract nature of the HL7 RIM and the inconsistency between the HL7 RIM and analysts' views of requirements for the LIMS. The results indicate that a methodology for developing health related systems compliant with the HL7 RIM may benefit from beginning with the standard and working toward the needs of the system versus beginning with the requirements for the system then integrating the standard.

Keywords

HL7, system development, health, standards, data modeling, prototyping.

INTRODUCTION

In this paper we describe a process followed in an attempt to integrate the HL7 RIM into a clinical Laboratory Information Management System (LIMS). The process of developing the requirements for the LIMS was performed by the authors with a senior systems analyst of the Veterinary Medical School (VMS) at a large university in the Eastern U.S. Although, the purpose of the project for the Information Systems department of the Veterinary School was development of the LIMS to support clinical studies using animals, they also were interested in learning about electronic health records for implementation within the large animal hospital that is their primary responsibility. In addition, the potential of leveraging the results of animal studies maintained in a form consistent with human trials, was appealing both to toxicologists and systems administrators in the VMS.

Standards organizations in many industries have been working to develop data exchange and messaging standards. Health Level 7 is such an organization and has been working since 1989 on the creation of an ontology that sufficiently describes the transactions and data that occur in healthcare settings. These transactions include not only the clinical aspects involved in treatment of patients, but include billing, inventory, and other features necessary for a hospital or clinic to operate. The HL7 RIM is highly abstract. This has the benefit of being flexible and potentially complete, but bears the cost of being substantially different from the types of concrete models with which analysts are familiar, e.g., entity-relationship diagrams. Compliance requires analysts to understand the perspective of the ontology, then to understand the data necessary to support perspective of the ontology. These standards-driven requirements must be integrated by analysts with the system requirements provided from users' perspectives, as defined in typical system development methodologies.

Methodologies designed to develop information systems include activities intended to aid developers in the processes of identifying system requirements, developing models of data and processes, converting models into designs, and implementing those designs (Jocabson, et al., 1999). However, most methodologies do not include explicit activities for adapting requirements, documentation, or coding conventions to comply with existing standards. Simply stating that all requirements necessary for the system must be identified, and suggesting how they can be identified and refined. From this orientation, the requirements of the standard are just another requirement, i.e., other systems that wish to exchange electronic heath records are actors and data exchanged are messages sent to actors.

Yet, the standard is intended to be inclusive of any needs of users of an information system in the domain. Implying that the size of the task of creating a system that meets users' needs is smaller than the task of creating a system that meets users' needs and is compliant with the standard. In situations were compliance is necessary for marketability or usability, it is not clear how best to achieve integration. For example, should a traditional methodology driven by users perspectives be applied or should an alternative approach that begins with the standard and strips away the elements not necessary to meet the needs of users be more efficient, or perhaps some other process.

This project is an attempt to understand the issues associated with integrating standards in the context of health systems, where a standard exists, the task of data management is substantial, and data exchange is critical to the success of organizations. The remainder of the paper consists of a description of the LIMS developed, brief overview of the HL7 RIM, the development process used on the project, and a discussion of the issues and problems encountered.

LABORATORY ANIMAL SYSTEM (LASY)

A requirements analysis and database schema was developed for a laboratory animal system (LASY). Stakeholders of LASY include investigators, lab technicians, pathologists, genomic technicians, and future researchers. Figure 1 provides an overview of the context of the system. Investigators use LASY to define the activities and measurements that are required for the study, monitor the progress of studies, and as a repository for all the data resulting from a study. Lab technicians use LASY to record all of the activities and measurements throughout a study. These activities include all things necessary to feed and maintain the health of lab animals, administering study treatments, measures of weight and blood chemistry, behavioral observations, and tissue sampling. Pathologists use the system to record the results of their evaluations of samples in accordance with protocol specifications. In Figure 1, LASY LAB is designed to be a simple-to-use system in a typical lab setting where the care and treatment regimen of the animals during one study is the primary concern. However, researchers often use common clinical measurement criteria across studies. This provides the potential to combine data across multiple studies to answer questions not initially considered. Future researchers could combine data across studies with common measures to answer questions through additional analyses, i.e., minimizing the need for conducting additional studies and focusing new studies where they have greatest potential.

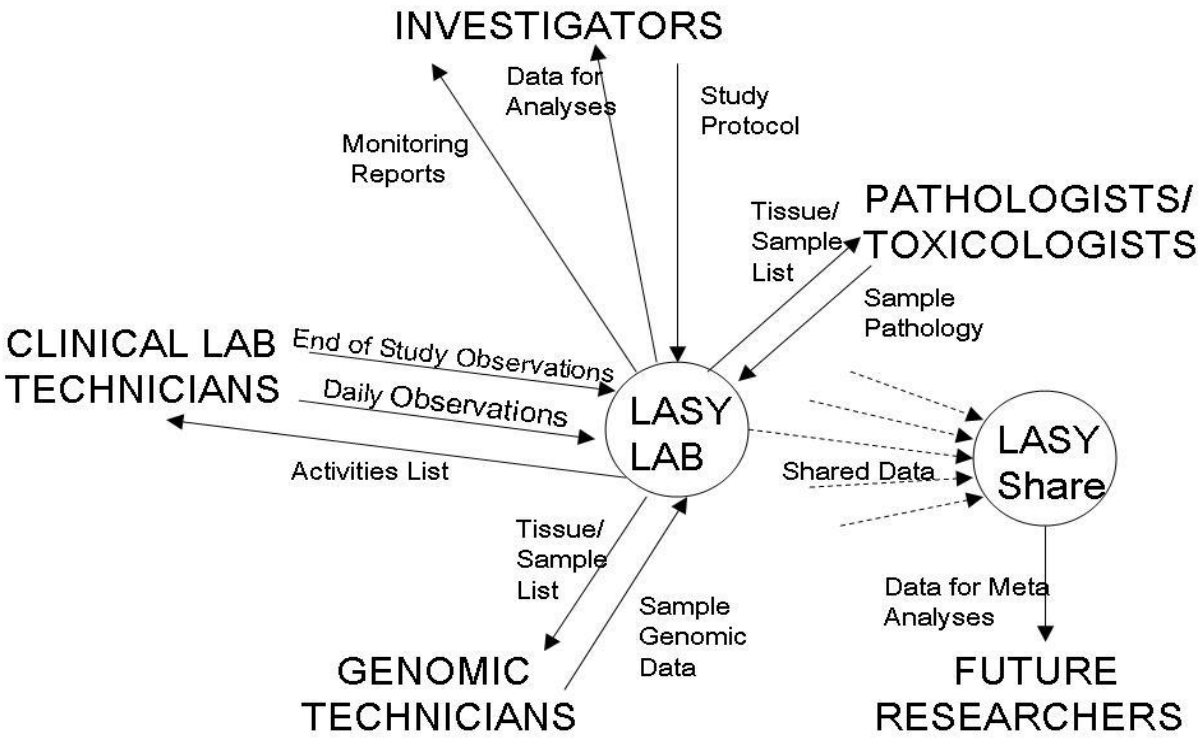

Figure 1. Context of LASY LIMS.

OVERVIEW OF HL7 RIM

The Health Level 7 (HL7) Standards Development Organization has recently been selected by the Department of Health and Human Services as the lead group in the creation of a standard model for electronic health records. The HL7 RIMv3 is in the process of being adopted as the new HL7 reference information model for clinical information (www.hl7.org). It is a data – centric model that contains many database entities, represented as classes from an object-oriented perspective. The core classes of the HL7 RIM are presented in Figure 2. The abstract nature of the HL7 RIM is captured in these classes. From the perspective of the HL7 RIM, every transaction in a health care environment is an act. An act is participated in by entities playing roles. Acts are related to other acts through Act Relationships.

For example, an instance of a person entity in the role of nurse participates in an act of observing (measuring) the weight of another instance of a person entity playing the role of patient. The model is an elegant representation of the real world in that the same instance of a person entity that played the role of nurse in one act, can play the role of patient in another act, and the any possible new activity can be accommodated through the creation of subclasses resulting in new types of entities, roles, participations, and acts as environmental conditions change.

Similar acts are necessary in a LIMS for clinical studies like LASY. Thus it seems appropriate to apply the HL7 RIM 3.0 in the LASY context. A search of LIMS vendors was conducted to identify systems that integrated HL7 RIM 3.0. Several vendors had considered this issue, but no existing LIMS systems that implement the HL7 RIM 3.0 were found. Implementing LASY using the HL7 standard provides the capability to conduct animal studies where the results are intended to be submitted to drug approval agencies, e.g., the Food and Drug Administration. In addition, it provides the ability to conduct human studies that are governed by a variety of rules associated with data management. Such a system is essential for leverage the knowledge from animal studies to improve human health.

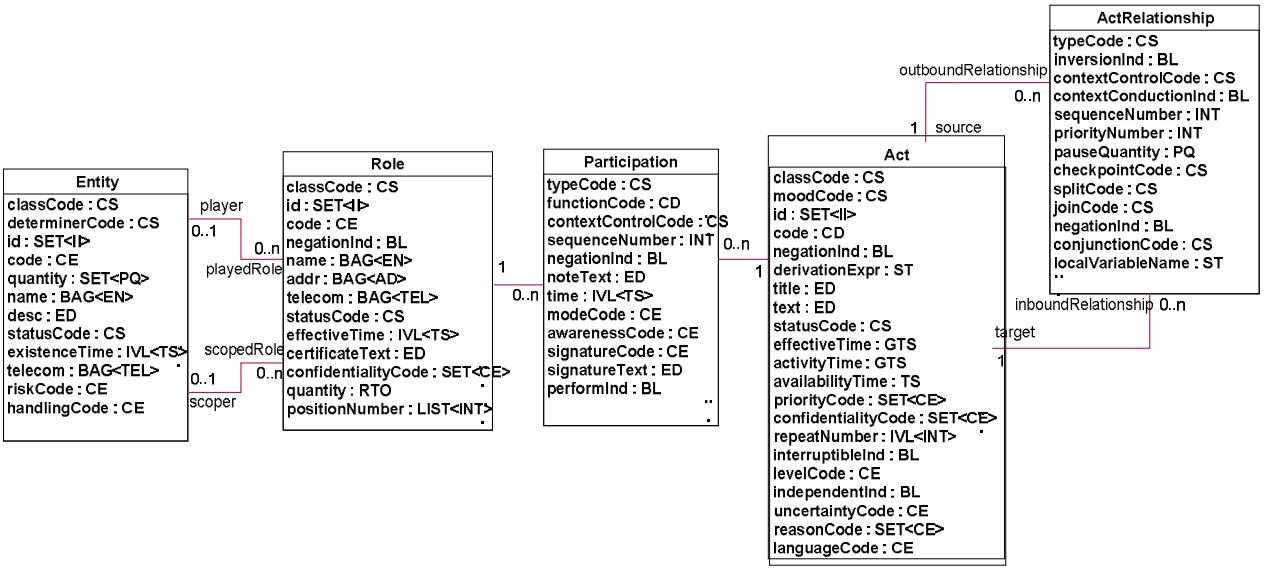

Figure 2. HL7 RIM Core Classes.

DEVELOPMENT PROCESS

The approach currently used to compile the data from clinical studies in this environment is study specific and time intensive. A LIMS is needed, yet costs of existing systems are prohibitive for the size of the organization and nature of the studies conducted.

The process of developing the requirements for the LASY LIMS was performed by the authors with a senior systems analyst of the Veterinary Medical School (VMS) at a large university in the Eastern U.S. The process applied consisted of the steps in Table 1. These steps are consistent with those recommended in Egahzy et al., 1998 and Egahzy and Murkherji, 2004.

Interviews with users of the LASY.
Evaluation of study documentation.
Development of Entity Relationship Diagram.
Development of LASY User-Interface prototype.
Review of Prototype User Interface with LASY users.
Evaluation of HL7 RIM.
Development of Revised ER Diagram Integrating HL7 RIM.
Implementation of LASY database (MySql).
Implementation of LASY Web-based Prototype (PHP).

Table 1. Steps in the Development Process

Requirements gathering consisted of interviews and evaluation of the documentation generated from previous clinical studies. Structured interviews (including open-ended questions) were conducted with the lab manager, two lab technicians, and one toxicologist. Interviews were focused to gain understand about the life cycle of a clinical study and the daily activities of technicians. The life cycle of study referred to defining experimental protocols, groups, blocks, treatments and measures to activities receiving animals, quarantine, health and behavioral observations, dosing, and care through concluding activities of sacrifice, tissue sampling, and pathology. The technicians received daily schedules of activities to be completed on various groups of animals arranged in blocks and groups. For example, one study analyzed consisted of 3 blocks, 16 groups per block, with 6 animals per group. Activities consisted of performing a variety of health measurements, e.g., weight and water consumption, along with batteries of behavioral tests, during and after creating conditions of stress, e.g., swimming. Training for technicians was highly specific and detailed for the protocol and measurements to be recorded for each test. Detailed paper check-sheets were developed to record the data in the lab and electronic spreadsheets were developed to record data electronically for export to statistical packages for analyses. Papers written from the study in toxicology journals were also evaluated to determine how the data were used and the analyses performed (Jortner et al., 2005).

A prototype of the user interfaces necessary to support the system was developed. The senior analyst walked-through the prototype interfaces with the lab manager to ensure that all necessary activities were included. The original entity-relationship diagram developed by the senior analyst and the authors is presented in Figure 3. The model includes all of the data necessary to satisfy the users' requirements for the system as determined by the senior analyst and the authors using the interviews and evaluation of previous study documentation. The senior analyst then resigned from the VMS (for reasons unrelated to the current project). With the need to replace the senior analyst and bring others quickly to fill her role in mission critical hospital information systems, the IS team at the VMS was forced to delay their continued participation in the project.

DISCUSSION

Two substantive issues emerged throughout the development process. First, and most importantly, the abstract nature of the HL7 RIM caused difficulties. The original ER diagram is similar to models made by experienced analysts in traditional situations, that is the focus is only on satisfying user needs rather than also complying with standards. Understanding how the highly concrete original ER diagram was consistent with the highly abstract HL7 RIM 3.0 proved difficult. Largely due to inconsistency in the terminology of the users and the conceptual structure of the HL7 RIM 3.0.

The abstract nature of the HL7 RIM was annoying to the senior analyst at the VMS. She did not accept the need to accommodate the entities-roles-participate-acts conceptual organization. Questioning whether the value of compliance was worth the additional development costs required to be compliant. She believed, and asserted, it would be more work to understand and integrate the standard into the system, than would be required to implement the entire (albeit non-compliant) system. In other words, she perceive the benefits of using the HL7 RIM 3.0 standard was not worth the costs.

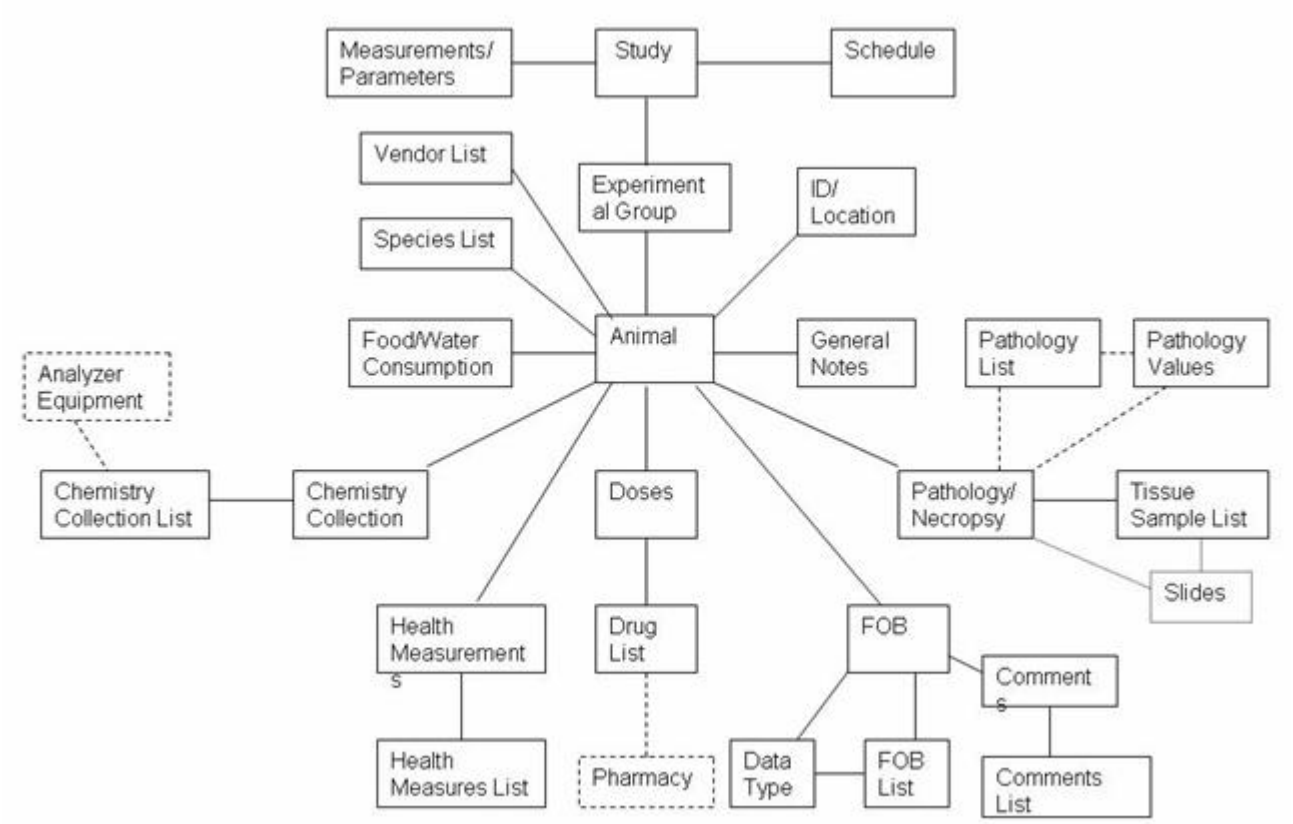

Figure 3. Original LASY ER Diagram.

Once the requirements for the LASY were complete the Health Level 7 Reference Information Model 3.0 (HL7 RIM 3.0) was evaluated. The decision to determine the needs of the lab technicians and toxicologists before evaluating the HL7 RIM were designed to ensure the needs of the clinical users were satisfied, as they would be the ultimate users

The authors then constituted a team of undergraduate students and began the task of adapting the ER diagram to be consistent with the HL7 RIM, create a MySQL database, and implement the prototype in PHP. The revised ER diagram is presented in Figure 4. This diagram is more abstract than the original diagram. Figure 3 is organized around the animal class. This is consistent with the views of the primary users of LASY, i.e., lab mangers and technicians. Figure 4 is organized around the observation entity, which is more consistent with the perspective of the HL7 RIM 3.0. The consistency of this observation entity with the HL7 RIM 3.0 perspective provides a more direct link between the database and the HL7 RIM than was possible with the original ER diagram.

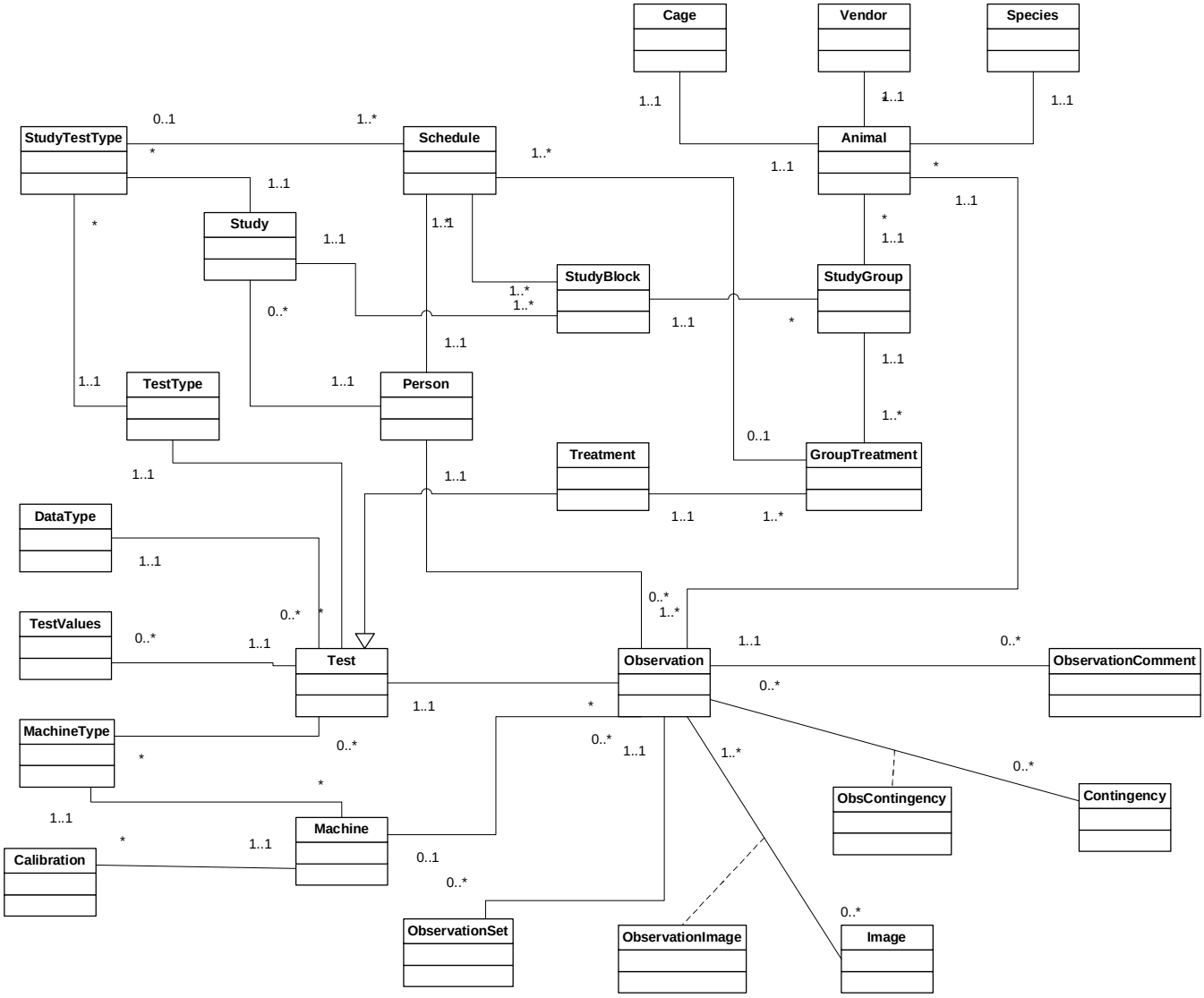

Figure 4. Revised LASY ER Diagram.

Student developers that gained their knowledge of the environment through interacting with the lab manager, reviewing the clinical documents, the original ER diagram and the user-interfaces also expressed difficulty with the entities-roles-participate-acts conceptual model. As a group they believed that being fully compliant with the HL7 RIM would mean not delivering a working system by the absolute deadline imposed by graduation.

The revised ER diagram is an attempt to bridge the concrete-abstract gap with a model at a level of abstraction that is between the original ER and the HL7 RIM 3.0. It was adopted by the team as easy enough to understand in terms of the clinical context and more clearly consistent with the HL7 RIM 3.0 through the observation act. However, substantive additional work is necessary for full compliance.

Users were insulated from the need to understand the entities-roles-participate-acts perspective by the user interface. The lab manager and technicians prioritized receiving the LASY as soon as possible above compliance with HL7 RIM 3.0. Toxicologists were interested in compliance in a conceptual manner, but were more interested on ensuring the completeness and correctness of the data for their studies. VMS administration, that was the prime stakeholder interested in the HL7 aspects of project, withdrew from the project due to lack of resources to participate.

Secondly, the methodology adopted for the development process could have contributed to the difficulties encountered. Perhaps developing a vision of the system that was independent of the HL7 RIM 3.0 made it more difficult to adapt to an HL7 RIM 3.0 compliant vision. In other words, the analyst and the authors had "solved" the problem. Thus the process of adapting the solution to accommodate the standard, seemed more like a new (and irrelevant to the senior analyst) and was seen as not useful.

Following a methodology that begins in the standard versus the direct needs of users seems at odds with many modern approaches (Jocabson, et al., 1999). However, such a process might be more likely to produce a compliant database. Although it is essential that compliance be transparent to users, i.e., they cannot be expected to start thinking of themselves of instances of entities playing roles and participating in acts.

CONCLUSION

The development of information systems is complicated by the inclusion of standards. Methodologies would be enhanced by explicitly specifying how in the development process standards can be integrated in the resulting systems. In this study, substantial difficulty was encountered due to the abstract nature of the HL7 RIM and the inconsistency between the terminology of the RIM and analysts' and users' views of requirements for the LIMS. The suggests that a methodology for developing health related systems may benefit from beginning with the standard and working toward the needs of the system versus beginning with the requirements for the users then integrating the standard.

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